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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,951	02/09/2004	Kim Gene Friesen	2664H-000019/US	8636

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,951	FRIESEN ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 25-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/04;12/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restrictions

Applicant's election with traverse of group II claims 17-24 in the reply filed on July 26, 2006 is acknowledged. Claims 1-16 and 25-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 26, 2006. The traversal is on the ground(s) that "The Examiner has given no reason for requiring an election of species and has not indicated what the Examiner considers a genus or species. However, although glycine and proline are different compounds, they are both amino acids. A search for one species in the Group will suffice for the other species in that group since they are both common amino acids that are classified together. The election requirement is therefore improper and should be withdrawn. This is not found persuasive because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, divergent subject matter restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 8/13/2004 and 12/27/2004 have been received and acknowledged.

Status of Claims

Claims 1-33 are pending.

Claims 17-24 are elected and are examined.

Claims 1-16 and 25-33 are withdrawn as being drawn to a nonelected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating degradation of cartilage tissue in animal , does not reasonably provide enablement for prevention of degradation of cartilage tissue in animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Nature of Invention

Claims 17-24 are drawn to a method of preventing degradation of cartilage tissue in animal by administering a cartilage degradation effective amount of glycine and proline. Prevention by decreasing cartilage abnormalities, comprising administering the glycine and proline. There is no one particular decreasing cartilage abnormalities is effective for every form of cartilage abnormalities. There is no one treatment, or combination of treatments, which provides prevention (not occurring even the first time) of fractures due to osteoporosis for example. How can one prevent a disease that has multiple etiologies, (some factors involve in cartilage degradation are genetics, body mass, trauma etc) the factors and mechanisms underlying the disease processes are still under investigation such as synovial enzyme, chrondrocyte enzymes, inflammatory cell enzymes, homeostatic mechanism (see Smith Degradative enzymes in osteoarthritis enclosed). Only through fundamental understanding of the enzymes that involve in the breakdown of the cartilage matrix will help in designing a drug that is capable of broadly affecting every representation of cartilage degradation to a degree where prevention can only occur to stop progression further once it occurs.

The state of the art and predictability

The state of the prior art is that it involves a myriad of diseases such as osteoarthritis, rheumatoid arthritis, osteochondrosis, degenerative joint disease, synovitis etc thus preventing or treating will include screening in vitro and in vivo to

determine the effect of the compound on the specific disease. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of skill in the art from accepting any therapeutic regimen on its face.

The amount of guidance and working examples

In the instant case, the specification exclusively disclosed limited testing data on in articular cartilage of the pig, such a provision does not offer broad support for unlimited cartilage degradation as discussed above. Further description is required to support such a claim encompassing the broad spectrum of prevention of cartilage degradation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **17-24** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **1-14** of U.S.

Patent Application No. **11199410**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Both sets of claims refer to preventing and or managing a cartilage condition in an animal administering at least one of glycine or proline in the current application (claims 17-24) and (claims 1-14) in the copending application. The current application claims anticipate the copending application claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 17-24 and copending application claims 1-14. The method recited in the claims are anticipatory of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Dioguardi US 5198,465.

Dioguardi teaches a composition comprising glycine for the treatment of collagen biosynthesis disorders resulting form precursor deficiency containing atleast one amino acid –glycine or proline as in claims 17, 19, and 23 in an effective amount to an animal is anticipated, as animals are vertebrates and has skeletal frame (bones), for the treatment of bone disorder is anticipated because different processes of maturation of collagen occur in bone, (thus reference teaches treatment of collagen biosynthesis)

which can result either from enzymatic or nonenzymatic processes. The enzymatic process involves activation of lysyl oxidase, which leads to the formation of immature and mature crosslinks that stabilize the collagen fibrils. Two type of nonenzymatic process are described in type I collagen for example also, different determinants of bone quality are interrelated, especially the mineral and collagen, and analysis of their specific roles in bone strength is difficult, making claim 18 anticipatory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dioguardi US 5198,465 in view of Meyer et al. US 5,827, 874.

Dioguardi teaches a composition comprising glycine for the treatment of collagen biosynthesis disorders resulting form precursor deficiency containing atleast one amino acid –glycine or proline as in claims 17, 19, and 23 in an effective amount to an animal is anticipated, as animals are vertebrates and has skeletal frame (bones), for the treatment of bone disorder is obvious variation of the teaching because different processes of maturation of collagen occur in bone, (thus reference teaches treatment of collagen biosynthesis) which can result either from enzymatic or nonenzymatic processes. The enzymatic process involves activation of lysyl oxidase, which leads to the formation of immature and mature crosslinks that stabilize the collagen fibrils. Two type of nonenzymatic process are described in type I collagen for example also, different determinants of bone quality are interrelated, especially the mineral and collagen, and analysis of their specific roles in bone strength is difficult, making claim 18 obvious.

Meyer et al. teach the use of proline to treat rheumatic pain having at leat 15 of proline in the tablet formulation, thus dry matter.

Both references however, did not teach the concentration of glycine , however, one of ordinary skill in the art would have combined the above cited references that would have resulted in the claimed subject matter, and would have expected a reasonable amout of success in doing so, because the above references teaches that glycine and proline are main amino acid needed in the diet for the formation of good bones, and also for the treatment of rheumatoid or inflammatory disease.

One of ordinary skill in the art would have been motivated to combine the teachings of the above prior art and give as a supplement to a pet ie a dog or a feline that is suffering from rheumatoid arthritis or a degenerative joint disorder.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 9/24/06

SVG

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER